May 1, 2019

ChoiceSpine, LP
Ms. Kim Finch
Director of Regulatory Affairs
400 Erin Drive
Knoxville, Tennessee 37919

Re: K190227
Trade/Device Name: Boomerang™ Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: February 1, 2019
Received: February 5, 2019

Dear Ms. Finch:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for CAPT Raquel Peat, PhD, MPH, USPHS
Director
Office of Health Technology 6
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K190227

Device Name
Boomerang™Anterior Cervical Plate System

Indications for Use *(Describe)*
The ChoiceSpine Boomerang™ Anterior Cervical Plate System is intended for anterior cervical fixation (C2-T1) for the following indications: degenerative disc disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion.

WARNING: This device is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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7. 510(k) Summary

Date:	February 4, 2019
Sponsor:	ChoiceSpine, LP 400 Erin Drive Knoxville, TN 37919
Phone:	865-246-3333
Fax:	865-246-3334
Contact Person:	Kim Finch, Director of Regulatory Affairs
Proposed Proprietary Trade Name:	Boomerang™ Anterior Cervical Plate System
Product Class:	Class II
Classification Name:	888.3060 - Spinal Intervertebral Body Fixation Orthosis
Device Product Code:	KWQ
Purpose of Submission:	The purpose of this submission is to gain clearance for a new anterior cervical plate and screw system.
Device Description:	The ChoiceSpine Boomerang™ Anterior Cervical Plate system is intended for anterior screw fixation to the cervical spine. The system consists of a variety of bone plates and screws made from titanium alloy (T-6Al-4V ELI) per ASTM F136 and a set of instruments made from stainless steels (455, 465 and 17-4) per ASTM A564 and ASTM F899. The system components are provided non-sterile and must be steam sterilized by the user prior to use.
Indications for Use:	The ChoiceSpine Boomerang™ Anterior Cervical Plate system is intended for anterior cervical fixation (C2-T1) for the following indications: degenerative disc disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion. WARNING: This device is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.
Summary of the Technological Characteristics	As established in this submission, equivalency of the ChoiceSpine Boomerang™ Anterior Cervical Plate system to its predicate devices is based on similarities in the indications for/intended use, design, product offering, materials used and levels of attachment.
Summary of the Performance Data:	Mechanical testing (static and dynamic compression bending and static torsion) per ASTM F1717-18 was performed to demonstrate that the ChoiceSpine Boomerang™ Anterior Cervical Plate system is substantially equivalent to its predicate devices. The test results indicate that the pre-defined acceptance criteria were met.

Conclusion: The ChoiceSpine Boomerang™ Anterior Cervical Plate system has the same indications, technological characteristics, and principles of operation as its predicates of traditional design. The proposed design differs from its predicates in that only one screw is required to be placed in each adjacent vertebral body as opposed to two. Despite this difference, the mechanical testing results and predicate data provided in Attachment 4 further demonstrate substantial equivalence to the predicate devices.

Predicate Devices:

Primary predicate: DePuy Synthes Anterior CSLP System (K030866)

Additional Predicates: ChoiceSpine Ambassador™ (K143576)
Eurosurgical, SA ORIA Zenith (K030500)
DePuy Motech AcroMed – DOC™ Ventral Cervical Stablization System (K982443)
Stryker Spine – Aviator Plate (K083562)